



DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35

Public Health Service

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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-03-39

August 5, 2003

Donald D. Metchick, President
Mid-Florida Bakeries, LLC
1016 West Concord Street
Orlando, Florida 32805

Dear Mr. Metchick:

The Food and Drug Administration (FDA) conducted an inspection of your bakery located at the above address on May 28 through June 11, 2003 and also on June 24, 2003, and found that you have serious deviations from Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (cGMP) regulations (21 CFR Part 110). At the conclusion of the inspection, you were issued a Form FDA-483, which delineated a large number of gross insanitary conditions present in your bakery at the time of the inspection. These conditions cause the bakery products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and these regulations through links in FDA's Internet home page at www.fda.gov.

The following is a list of insanitary conditions observed by our investigators during the inspection.

1. Rodent activity was observed in the processing area, on food contact surfaces, and on raw material in the bakery:
[21 CFR 110.35(c)]
 - During the inspection on May 30, 2003, two live rats were seen running across the loading/receiving area;
 - Two (2) dead rats were observed inside the rat bait station;
 - One (1) dead mouse was observed on the floor behind the baking oven in the processing area;
 - Dead mice were observed on glue boards and ceiling areas directly above the processing room;
 - Bread slicers, table surfaces, and bread trays used during processing, all fluoresced under black light indicating rodent urine stains;
 - Raw material packaging, including [REDACTED] Brown Sugar and [REDACTED] Bread Mix, fluoresced under black light indicating rodent urine staining;

- Numerous rodent excreta pellets were observed in the processing and receiving areas. Sample 212035, consisting of thirty-one (31) excreta pellets, collected from ledge lining the inner wall of the receiving dock and Sample 212036, consisting of twenty (20) excreta pellets, collected from the production office adjacent to the bakery production area were confirmed as rodent excreta by our FDA laboratory.
2. Live insect activity was observed on raw materials, unfinished baked goods, food contact surfaces, processing equipments, and in processing areas: [21 CFR 110.35(c)]
- During the inspection on May 29, 2003, numerous live sewer flies and gnats were observed in the processing area near the floor drain, on top of food contact surfaces, on processing equipment, raw product, and packaging material;
 - Approximately ten (10) live cockroaches were observed on the floor and walls of the processing area;
 - Numerous ants were observed on triple-bay sink ledges, processing tables/equipment, and processing areas;
 - Samples 212035, 212036, and 212037 collected during the inspection and examined by our FDA laboratory confirmed the presence of numerous fly species, cockroaches and ants.
- Failure to take adequate steps to ensure that bakery products are manufactured in accordance with 21 CFR 110. Specifically, our investigators observed manufacturing conditions that render these products unfit for human food and cited conditions indicating that these products were prepared, packed or held under insanitary conditions, whereby they may become contaminated with filth or rendered injurious to health: [21 CFR 110]
- Manufacturing and baking equipment was improperly cleaned, rinsed, and sanitized before beginning production. Specifically, all processing equipment was encrusted with yellow-brown residues that also encased and covered the exterior of the equipment. Mold and a yellow-brown sticky, oily film were observed on equipment, belts, and rollers that came into contact with raw dough and finished bakery products. The equipment was rusted, corroded, and held together with tape and shoestrings making adequate cleaning and sanitizing impossible. By your own admission, you stated that you did not perform thorough cleaning and maintenance on the inherited equipment, previously used by the European Bakery, before beginning your processing operations. [21 CFR 110.40(a) / (c)]
 - The ice trays and ice machine, used to form ice which came into direct contact with both raw and finished products, contained mold and mildew. Black, slimy mold was observed on the inside of ice cube trays. Ice from

- these trays was placed into raw dough to develop the dough and used to release finished breads from baking pans in ice baths used for cooling the products. The scoop used to dispense ice from the machine was encrusted with dough and flour residue. [21 CFR 110.80(b)(16)]
- Loaf pans and baking trays were observed to be encrusted with a thick, black oily residue. Finished breads were placed on stainless steel, ventilated metal racks which were encrusted with oil, bread residue, and dust which stuck together creating suspended deposits between the vents in the rack. Employees were observed, without gloves or proper hand-sanitization, taking the finished loaves of bread from these racks, placing them on the rodent-urine stained slicer, and transferring the loaves into plastic bags with color-coded twist ties. [21 CFR 110.80(b)(6)]
- Baking pans were observed being placed into an open pit and being “washed” with a gasoline powered high pressure washer. A non-food grade degreasing agent, [REDACTED] containing toxic ethylene glycol, was being used to “clean” the pans. There was no evidence of any type of sanitizer being used during the cleaning process. [21 CFR 110.35(d)(5)]
- On May 28, 2003, all hand-washing stations were observed to be clogged or stopped-up by our investigations. The sinks in the rest rooms, processing area, and finished product packing rooms lacked hand-washing signs, soap, hot water, paper towels, or trash receptacles. [21 CFR 110.10(b)(3)/110.37(e)]
- Ventilation duct vents in the processing areas were encrusted with filth and dirt. Our investigators reported that as the air flowed through these ventilation ducts, small debris and dust could be seen falling on raw and finished products. [21 CFR 110.20(b)(6)]
- Our investigators observed inadequate lighting in the processing area, loading dock, and warehouse. Seven (7) lighting fixtures in the processing room lacked safety covers, and a general lack of adequate lighting throughout the facility made it difficult to determine whether proper cleaning and sanitization was being conducted on all processing equipment. [21 CFR 110.20(b)(5)]
- Inappropriate storage of raw materials with old equipment, paint, and various chemicals was observed during the first several days of the investigation. The accumulation of dirty equipment and piles of rubbish throughout the facility hindered the ability to access various areas in the plant for general cleaning and pest control. [21 CFR 110.35(b)(2) / 110.20(b)(1)]
- Numerous holes were observed in the walls and ceiling of the facility. Holes in the walls and ceiling lead to the exterior of the building and an uncovered

ventilation tube from the roof into the building provided direct entry for rodents and insects. [21 CFR 110.20(b)]

- The receiving dock door, entrance door, and disposal unit door on the northeast side of the plant contained large holes and gaps, allowing entry of pests. During the collection of the waste disposal container on May 29, 2003, our investigators observed numerous mice running underneath and around the container. A heavy accumulation of discarded food remained, after the collection of this container, due to the fixed waste chute from the plant being too short to adequately empty into the trash receptacle. [21 CFR 110.37(f)]
- During the inspection, open bait boxes containing toxic bait were observed in the receiving dock area. Our investigators observed pesticide powder covering bait station #13 near the three-bay sink and bait station #15 located next to the ice machine in the processing area. Further examination of a bait station located on the southwest side of the processing area, revealed that the bait station had not been examined since April, 2002. [21 CFR 110.35(c)]

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and all applicable Good Manufacturing Practice Regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. We may, without further notice, take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from receipt of this letter. Your response should outline the specific things you are doing to correct and prevent the recurrence of these deviations. You may wish to include documents in your response that support your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct the remaining deviations.

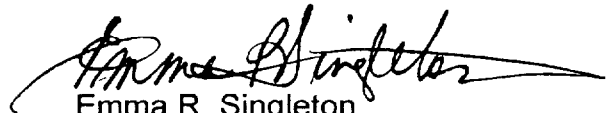
For your information, a review of the Nutrition Facts information collected by our investigators for bulk formulated bakery mixes supplied by [REDACTED] can only be used for the bulk raw material itself. Recipes collected from your firm indicate that these mixes are only a small portion of the total formulation of various products manufactured by your firm. By your own admission, you informed our investigators that when customers request Nutrition Facts information on your products, you supply them with the [REDACTED] data only. The Nutrition Facts information provided by [REDACTED] states that their data is not a substitute for an analysis of a product which is formulated using their mixes as one component in a recipe. As stated by [REDACTED] on their labels, the ultimate responsibility for compliance with 21 CFR 101.9, nutrition labeling of food (NLEA), for the final product rests with the baker. Your products are misbranded within the meaning of Section 403 of the Act, if you are using

the nutritional information from one of your finished product ingredients as the sole source of nutritional information for the finished products.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751.

If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District

Enclosure:
Form FDA 483